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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,089	08/26/2003	Samuel H. Gellman	09820.286	2777
25005	7590	05/05/2006	EXAMINER	
DEWITT ROSS & STEVENS S.C.			KOSAR, ANDREW D	
8000 EXCELSIOR DR			ART UNIT	
SUITE 401			PAPER NUMBER	
MADISON, WI 53717-1914			1654	

DATE MAILED: 05/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/648,089	Applicant(s) GELLMAN ET AL.	
	Examiner Andrew D. Kosar	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-6, 8, 9 and 11 is/are pending in the application.
- 4a) Of the above claim(s) 8, 9 and 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 2, 2006 has been entered.

Claims 4-6, 8, 9 and 11 are pending. **Claim 11** remains withdrawn for the reasons of record. **Claims 8 and 9** are withdrawn for the reason below.

Claims 4-6 have been examined on the merits.

Information Disclosure Statement

The information disclosure statement filed February 2, 2006, submitted as 'Exhibits', fails to comply with 37 CFR 1.98(a)(1), which requires the following: (1) a list of all patents, publications, applications, or other information submitted for consideration by the Office; (2) U.S. patents and U.S. patent application publications listed in a section separately from citations of other documents; (3) the application number of the application in which the information disclosure statement is being submitted on each page of the list; (4) a column that provides a blank space next to each document to be considered, for the examiner's initials; and (5) a heading that clearly indicates that the list is an information disclosure statement.

The information disclosure statement has been placed in the application file, but the information referred to therein has not been considered.

Response to Arguments / Amendments

Applicant's arguments and amendment to the specification filed February 2, 2006 are acknowledged.

In view of Applicant's amendment to the specification, the rejection of **claims 4-6, 8 and 9** under 35 USC § 112, 1st paragraph (written description) and 35 USC § 102(b) as being anticipated by Appella, is withdrawn, as the definition of α -amino acids no longer reasonably includes β -amino acids.

In accordance with MPEP § 803.02, the examiner extended the search as set forth below, to the species Ac-Val-Nip-Nip-Leu-N(Me)₂ which is readable upon claims 4-6, and thus claims 8 and 9 are withdrawn from consideration as not being readable upon the examined species.

Any rejection and/or objection not specifically addressed is herein withdrawn.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4-6 remain rejected under 35 U.S.C. § 101, for the reasons of record and those set forth below, because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility.

Claims 4-6 remain rejected under 35 U.S.C. § 112, first paragraph (enablement), for the reasons of record. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth under 35 USC § 101, one skilled in the art clearly would not know how to use the claimed invention.

Because Applicant argues the rejection under 35 USC §§ 101 and 112, 1st paragraph, simultaneously, as the rejection under § 112, 1st paragraph, is predicated entirely upon the rejection under § 101, the examiner will address Applicant's remarks in kind.

Applicant's arguments have been considered but have not been found persuasive.

Applicant argues at length that the compounds are supported by a credible, substantial and specific utility. Applicant disagrees with the Examiner regarding Seebach, and requests clarification as to why the Examiner does not agree that Seebach provides 'a well known utility'.

With regards to Seebach, the Examiner did not 'elevate form over function', but considered the disclosure of Seebach to be inapplicable, as the compounds of Seebach are γ -dipeptides, while the instantly claimed compounds are, at minimum, tetrapeptides with at least 1 α -amino acid and at least 2 cyclically constrained β -amino acids. The compounds are not coextensive or commensurate in scope, and thus cannot provide a 'well established utility' for the instant compounds based upon structure and amino acid content.

Furthermore, Seebach merely provides further evidence that the compounds are not of a well established utility, as even Seebach states that the results, "promise a potential of γ -peptides for the development of peptidase-resistant peptidomimetic drugs." (page 777, last paragraph). Seebach makes no reference or inference that the compounds relate to tetrapeptides (or larger) with α and cyclically constrained β -amino acids that are instantly claimed.

More recently, SCHMITT (M.A. Schmitt, et al. J. Am. Chem. Soc. (2005) 127, pages 13130-13131) teaches compounds which are of a similar structure to those of the instant application (e.g. compound 1). Schmitt, while not contemporaneous with the instant application, provides that the art still does not provide a 'well established' utility, as Schmitt teaches that,

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“Foldamers of this type [α/β -peptides] might mimic recognition surfaces on proteins and thereby disrupt specific protein-protein interactions [citing Sadowsky (2005)] or perform multifunctional catalysis of chemical reactions.” (page 13131, last paragraph). These are general utilities, not specific as required by the statute.

Furthermore, while Applicant asserts that a compound library is a “useful endeavor” (page 20, *Remarks*), it does not meet the requirements of § 101, and thus § 112, 1st paragraph. Disruption of protein-protein interactions is a generic utility, and the questions that arise are, “which specific protein-protein interactions are contemplated and disclosed to be disrupted by Applicant?” and, “to what end are the interactions disrupted (e.g. increasing clot formation, preventing angiogenesis, increasing milk production, etc.)?” The specification is silent to any specific protein-protein interaction that is disrupted or what is the effect of the disruption.

While chemical libraries are commercially available, they are sold as research tools, which are clearly delineated by MPEP § 2107.01(I) as being a utility which is not substantial (*see, e.g. page 7, Office Action mailed 5/4/05*). It is noted that the Exhibits do not discuss the particulars of the instant invention, e.g. examples of the instantly claimed compound, but rather generalizations on peptide libraries. Furthermore, as stated in the previous office action the MPEP states, “An assessment that focuses on whether the invention is useful only in a research setting thus does not address whether the invention is in fact “useful” in a patent sense. Instead, Office personnel must distinguish between inventions that have a specifically identified substantial utility and inventions whose asserted utility requires further research to identify or reasonably confirm.” (Emphasis added; *see page 7, Office Action mailed 5/4/05*).

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Furthermore, MPEP § 2107 (II)A(3) (the Examination Guidelines for the Utility Requirement) sets forth the test for determining a 'well established utility', stating, "If at any time during the examination, it becomes readily apparent that the claimed invention has a well-established utility, do not impose a rejection based on lack of utility. An invention has a well-established utility if (i) a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (e.g., properties or applications of a product or process), and (ii) the utility is specific, substantial, and credible." (emphasis added). A 'well-established' utility requires that the utility is specific, substantial and credible, and not a 'general' utility, as is the case in the instant application because there is no specifically identified substantial utility and the invention requires further research and testing to determine what specific protein-protein interactions may be disrupted with the compounds of the instant invention.

New Grounds of Rejection / Objection

Please note, while the examiner has made every effort to identify the errors within the specification, the lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claims 4 and 6 are objected to for the following informalities:

Claims 4 and 6 each recite a generic chemical formula with A representing both the N- and C- termini, where one should be designated separately, e.g. A' for the C-terminus, to distinguish between the N- and C- terminus variables.

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Additionally, the definitions of X and Z are indistinguishable one from another in the claim bodies, differing only by the number of independent units (a and c), and should be amended to be a single entity, e.g. X.

Appropriate correction is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites, “each X and each Z is independently variable and is selected from the group consisting of α -amino acid residues, β -amino acid residues, and γ -amino acid residues, provided that at least one X or Z comprises an α -amino acid residue and at least another two of X or Z comprise two cyclically constrained β -amino acid residues;...” (emphasis added) which is unclear and indefinite.

The claim does not allow for X and/or Z to ‘comprise’ anymore than a single amino acid, as the introductory recitation is that each X and each Z is..., while comprising allows for 1 or more amino acids, or other moieties, to be present.

Claims 4 and 6 recite, “wherein each cyclically-constrained β -amino acid residue is independently selected from the group consisting of...and the substituents listed above for V and W when V and W are not combined;” which is unclear and indefinite, as it is unclear how, if the residue is cyclically constrained how V and W can be anything but ‘combined’.

Claims 4 and 6 recite, “and salts thereof”, which is unclear and indefinite, as it is unclear whether Applicant is claiming the compound and the salts together (e.g. a composition claim), or

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whether Applicant intended to claim the compound or the salts thereof in the alternative (e.g. compound X or a salt of compound X).

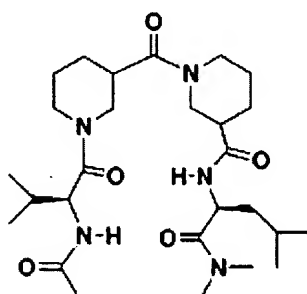
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

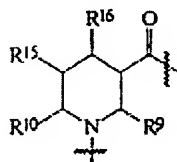
Claims 4-6 are rejected under 35 U.S.C. 102(b) as being anticipated by HUCK (B.R.

Huck, et al. Organic Letters (2000) 2(17), pages 2607-2610).



Huck teaches the compound: , which can be written as Ac-Val-

Nip-Nip-Leu-N(Me)₂. Ac is an N-protecting group, Val and Leu are both α -amino acids, Nip is the 'cyclically constrained β -amino acid residue'.



Nip is , wherein each R^{9,10,15 and 16} is hydrogen, as defined in the instant

claim (pages 6 and 9).

Conclusion

The prior art made of record on the attached PTO-892 and not relied upon in any rejection is considered pertinent to applicant's disclosure.

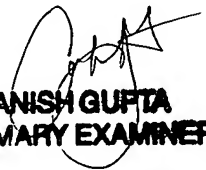
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 8am-430pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Andrew D. Kosar, Ph.D.
Art Unit 1654


ANISH GUPTA
PRIMARY EXAMINER